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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,341	06/09/2006	Sung Youb Jung	430156.401USPC	7156

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EXAMINER
DAHLE, CHUN WU

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,341	JUNG ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15* is/are pending in the application.

4a) Of the above claim(s) *8-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 13, and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/25/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on September 4, 2009, has been entered.

2. Applicant's amendment to the claims, filed on September 4, 2009, has been entered.
Claim 14 has been canceled.
Claim 15 has been added.

Claims 1-13 and 15 are pending.

Claims 8-12 stand withdrawn from further consideration by the Examiner, under 37 C.F.R. 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 15, 2008.

Claims 1-7, 13, and newly added claim 15 are currently under consideration as they read on the elected invention of an Fc fragment and SEQ ID NO:8.

3. This Office Action will be in response to applicant's arguments, filed on December 10, 2008 and September 4, 2009.

The rejections of record can be found in the previous Office Action, mailed on June 10, 2008 and March 4, 2009.

4. Applicant's IDS, filed on September 25, 2009, is considered.

5. In view of applicant's amendment to the claims, the prior rejection under 35 U.S.C. 102(b) based upon Maddon et al. (US Patent 6,034,223, reference of record) has been with drawn.

6. In view of applicant's amendment to the claims, the prior rejection under 35 U.S.C. 103(a) based upon Maddon et al. (US Patent 6,034,223, reference of record) in view of Presta (US Patent 6,737,056, reference of record) has been with drawn.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-7, 13, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-7, 13, and 15 are indefinite in the recitation of "which is an IgG Fc, a combination thereof or a hybrid thereof" because the metes and bounds of the "combination thereof or a hybrid thereof" is ambiguous. It is not clear how a combination of Fc is made and what constitutes a hybrid. Therefore, the claims fail to particularly point out and distinctly claim the subject matter.

B) Claim 6 is indefinite in the recitation of "IgG4 Fc fragment is human-derived" because the metes and bounds of the claimed Fc fragment is unclear and ambiguous. It is not clear how an Fc fragment can be derived from human.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 is drawn to a pharmaceutical composition comprising the Fc fragment as a drug carrier, wherein the Fc fragment is covalently linked to a drug.

The specification discloses that the drug encompassed by the claimed pharmaceutical composition includes human growth hormone, growth hormone releasing hormone, or growth hormone releasing peptide (e.g. see pages 30-31 of the instant specification).

The specification as-filed does not enable one skilled in the art to practice the claimed invention without undue amount of experimentation.

There is insufficient evidence in the instant specification to support the make and use of a pharmaceutical composition comprising a an Fc fragment covalently linked to any drug commensurate in scope with these claims.

It is noted that the recited "pharmaceutical composition" has the intended uses for prevention, diagnosis or treatment of diseases in human and animals. Thus, to enable such claims, the specification must teach how to use the composition without undue experimentation for prevention, diagnosis, and treatment of diseases in human and animals. However, the instant specification fails to teach how to make and use a "pharmaceutical composition" as claimed.

Polymer conjugation of drugs for therapeutic uses can be unpredictable since aggregation and immunogenicity can occur during purification and storage (see page e2 of Veronese et al. Drug Discovery Today: Technologies 2009 doi:10.1016/j.ddtec.2009.02.002. Pages e1-e8). In addition, PEGylation can reduce enzymatic activity or receptor recognition (e.g. see page e5 of

Veronese et al.). Given that it is not clear what the claimed drug is, one of skill in the art would not be able to determine whether an Fc fragment covalently linked to a drug can be formulated into a "pharmaceutical composition" for the intend *in vivo* uses.

Furthermore, pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

Given that the specification does not provide sufficient guidance or direction with respect to the make and use the drug including human growth hormone, growth hormone releasing hormone, or growth hormone releasing peptide, one of skill in the art would not be able to produce and use the claimed pharmaceutical composition comprising an Fc region covalently linked to any drug for the intend *in vivo* uses.

Amending the claims to recite “composition” rather than "pharmaceutical composition" would obviate this rejection.

11. Claims 1-7, 13, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The recited "wherein the non-peptide linker comprises polyethylene glycol ..... or combination thereof" as recited in claims 1-7, 13, and 15 is not supported by the original disclosure or claim as filed.

Applicant's amendment, filed on September 4, 2009, directs to support to page 33, and asserts that no new matter has been added.

However, the specification as filed does not provide sufficient written description of the above-mentioned combination of different non-peptide linker or non-peptide linker that is open with additional elements. The specification only discloses non-peptide linker that is polyethylene glycol etc as recited in claim 1; the instant claims now recite "wherein the non-peptide linker comprises polyethylene glycol ..... or combination thereof", which were not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure (non-peptide linker) and possibly limited species of linkers such as polyethylene glycol do not provide sufficient direction and guidance to the features currently claimed ("wherein the non-peptide linker comprises polyethylene glycol ..... or combination thereof"). It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679 683 (CCPA 1972) and MPEP 2163.05.

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the

"limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-7, 13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Kostenuik et al. (US Patent 6,756,480).

Kostenuik et al. teach parathyroid hormone peptide (PHP) covalently linked to an Fc domain via a linker (e.g. see claims 1-3). Kastenuik et al. further teach that said linker can be non-peptide linker such as PEG linker (e.g. see Linkers defined on columns 33-34). Further, Kastenuik et al. teach that said Fc domain can be human IgG1, 2, 3, or 4 and aglycosylated (e.g. see columns 8-9 and 31-32). Furthermore, Kastenuik et al. teach pharmaceutical composition comprising said PHP covalently linked to an Fc (e.g. columns 39-40). Given that the recited SEQ ID NO:8 is the amino acid sequence of the Fc region of human mature IgG4, the prior art Fc region from human IgG4 would read onto the instant claim 7 encompassing SEQ ID NO:8.

Therefore, the reference teachings anticipate the claimed invention.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-7, 13, and newly added 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending USSN 10/535,231 and claims 1-19 and 27-45 of copending USSN 10/535,232 for reasons of record.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that no terminal disclaimer signed by the assignee and fully complied with 37 CFR 3.73(b) was filed, the provisional rejection on the ground of nonstatutory obviousness-type double patenting is maintained.

16. Claims 1-7, 13, and newly added 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 and 24

of copending USSN 11/747,153 and claims 1-25 of copending USSN 11/910,962 and claims 1-26 and 33 of copending USSN 11/947,697.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant and the copending applications claims are drawn to the same or nearly the same composition comprising IgG Fc fragment. As such, the species recited in the copending claims (e.g. an insulinotropic peptide conjugate in USSN 11/947,697) would anticipate or render obvious of the instant claims encompassing a genus of drug covalently linked to an Fc region.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-7, 13 and 15 are directed to an invention not patentably distinct from claims 1-19 and 24 of commonly assigned copending USSN 11/747,153 and claims 1-25 of commonly assigned copending USSN 11/910,962 and claims 1-26 and 33 of commonly assigned copending USSN 11/947,697 for reasons stated above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned USSNs 11/747,153, 11/910,962, and 11/947,697, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the

invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chun Dahle/
Examiner, Art Unit 1644